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10/587,085	07/21/2006	Satohiro Yanagisawa	5404-161	7677

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,085	YANAGISAWA ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0706;1106;0608*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are pending.

Claims 1-17 share a special technical feature directed to the polypeptide of SEQ ID NO: 1, the encoding polynucleotide of SEQ ID NO: 3, host cells thereof, and methods of making the polypeptide of SEQ ID NO: 1. Claims 1-17 are herein examined.

Priority

The priority date granted for the instant invention is January 26, 2005, the filing date of PCT/JP05/00951, which disclosed the elected invention. If Applicants wish to perfect their claim to priority to JP 2004-028041, filed February 4, 2004, an English translation thereof should be filed.

Information Disclosure Statement

Some references listed on the Information Disclosure Statement filed June 24, 2008 have not been considered because they have not been provided to the Examiner (see strikeouts). If Applicants wish for said references to be considered, a supplementary Information Disclosure Statement and the references should be filed. Any rejection based on said references will not be considered to be new grounds for rejection.

Claims-Objections

For Claim 14, line 1, "producing amidase" should be corrected to "producing an amidase".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The polypeptides and polynucleotide encompassed by said claims occur in nature; thus, the recited invention fails to show the "hand of man". It is suggested that the term "isolated" or "recombinant" be used.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 1, line 1, the term "having" renders the claim indefinite. It is unclear whether said term means "comprising" or "consisting of". The skilled artisan would not know the metes and bounds of the recited invention. Claims 2-4, 12-14, 16, and 17, as dependent from Claim 1, are indefinite for the same reason. For purposes of examination, it is assumed that "having" means "comprising".

For Claim 1, line 2, the phrase "an amino acid sequence of SEQ ID NO: 1" renders the claim indefinite. It is unclear whether the claim is meant to recite "the" amino acid sequence of SEQ ID NO: 1 or "any" amino acid sequence of SEQ ID NO: 1. The latter would encompass

peptides as small as two residues. Claims 2-4 and 12-17, as dependent from Claim 1, are indefinite for the same reason. For purposes of examination, it is assume that Claim 1 is meant to recite the amino acid sequence of SEQ ID NO: 1.

For Claim 5, lines 1 & 9, the term "having" renders the claim indefinite. It is unclear whether said term means "comprising" or "consisting of". The skilled artisan would not know the metes and bounds of the recited invention. Claims 6-11 and 15, as dependent from Claim 5, are indefinite for the same reason. For purposes of examination, it is assumed that "having" means "comprising".

For Claim 5(a)&(c), the phrase "a nucleotide sequence of SEQ ID NO: 3" renders the claim indefinite. It is unclear whether the claim is meant to recite "the" nucleotide sequence of SEQ ID NO: 3 or "any" nucleotide sequence of SEQ ID NO: 3. The latter would encompass nucleic acids as small as two residues. Claims 6-11 and 15, as dependent from Claim 5, are indefinite for the same reason. For purposes of examination, it is assume that Claim 5 is meant to recite the nucleotide sequence of SEQ ID NO: 3.

Claim 5 is indefinite in the recitation of "hybridizes under stringent conditions" as this phrase is unclear absent a statement of the conditions under which the hybridization reaction is preformed. Nucleic acids that will hybridize under some hybridization conditions, will not necessarily hybridize under different conditions. Claims 6-11 and 15, as dependent from Claim 5, are indefinite for the same reason.

Claims 15 and 16 are rendered indefinite for being dependent from more than one claim.

Claim 5 is rendered indefinite for improper antecedent usage as follows.

For Claim 5, the phrase "a DNA having a nucleotide sequence that is complementary to the nucleotide sequence of SEQ ID NO: 3" should be corrected to "a DNA having the nucleotide sequence that is complementary to the nucleotide sequence of SEQ ID NO: 3".

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the amidase of SEQ ID NO: 1 and the encoding polynucleotide of SEQ ID NO: 3, does not reasonably provide enablement for any variant of SEQ ID NO: 1 having amidase activity or any polynucleotide encoding any such variant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill

of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 1-3 are so broad as to encompass any polypeptide, comprising any variant of SEQ ID NO: 1 having any structure, wherein the polypeptide has amidase activity. Claims 4 and 5 are so broad as to encompass any nucleotide sequence (i) encoding any polypeptide, comprising any variant of SEQ ID NO: 1 having any structure, wherein the polypeptide has amidase activity, (ii) that hybridizes with any DNA comprising a sequence that is complementary to SEQ ID NO: 3 and (iii) comprising any variant of SEQ ID NO: 3 having any structure, wherein the nucleotide sequence encodes a polypeptide having amidase activity. It is noted that by use of "comprising" language, these claims encompass polypeptides/polynucleotides, wherein the activity is not derived from the sequence homologous to SEQ ID NO: 1 or 3.

The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides and polynucleotides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired amidase activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 1 and the nucleotide sequence of SEQ ID NO: 3.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 1-3, which encompasses all polypeptides, comprising any variant of SEQ ID NO: 1 having any structure, wherein the polypeptide has amidase activity. The specification does not support the broad scope of Claims 4 and 5, which encompasses all nucleotide sequences (i) encoding any polypeptide, comprising any variant of SEQ ID NO: 1 having any structure, wherein the polypeptide has amidase activity, (ii) that hybridizes with any DNA comprising a sequence that is complementary to SEQ ID NO: 3, and (iii) comprising any variant of SEQ ID NO: 3 having any structure, wherein the nucleotide sequence encodes a polypeptide having amidase activity. The specification does not support the broad scope of Claims 1-5 because the specification does not establish: (A) regions of the protein structure which may be modified without affecting the amidase activity; (B) the general tolerance of the amidase activity to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Since Claims 5-17 further recite vectors, host cells and methods of producing the recited polypeptides, Claims 5-17 are also rejected under 35 U.S.C. 112 first paragraph due to lack of enablement for the same reasons discussed above.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of polypeptides with an enormous number of amino acid modifications of the polypeptide of SEQ ID NO: 1 and any number of polynucleotides with an enormous number of amino acid modifications of the polynucleotide of SEQ ID NO: 3, as well as methods for making and using thereof. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of polypeptides and polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 3, 8, 11, 13, and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention of said claims employs a novel plasmid (Claim 8) or novel cells (Claims 3, 11, 13, and 15). Since the plasmid and cells are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plasmid and cells.

If the deposit is/was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;

2. upon granting of the patent the plasmid and cells will be available to the public under the conditions specified in 37 CFR 1.808;

3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

4. the deposit will be replaced if it should ever become inviable.

Written Description

Claims 1-3 and 12-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 1-3 are directed to a genus of polypeptides, comprising any variant of SEQ ID NO: 1 having any structure, wherein the polypeptide has

amidase activity. The specification teaches the structure of only a single representative species of such polypeptides. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being an amidase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention. Claims 12-16, as encompassing methods for making or using said polypeptides, are not described for the same reason.

Claims 4-11, 15, and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 4 and 5 are directed to a genus of nucleotide sequences (i) encoding any polypeptide, comprising any variant of SEQ ID NO: 1 having any structure, wherein the polypeptide has amidase activity, (ii) that hybridizes with any DNA comprising a sequence that is complementary to SEQ ID NO: 3, and (iii) comprising any variant of SEQ ID NO: 3 having any structure, wherein the nucleotide sequence encodes a polypeptide having amidase activity. The specification teaches the structure of only a single representative species of such nucleotide sequences. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding an amidase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants

were in possession of the claimed invention. Claims 6-11, 15, and 17, as encompassing methods for making or using said polynucleotides, are not described for the same reason.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-7, 9, 10, 14, 15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Barton et al, 2004 (filing date 28-JAN-2003). Barton et al teaches a polypeptide that is a variant of SEQ ID NO: 1 and has amidase activity. Barton et al also teaches a polynucleotide that is a variant of SEQ ID NO: 3, encodes a variant of SEQ ID NO: 1, and has amidase activity. Barton et al further teaches vectors (including pBR322) and microorganisms (including E. coli) comprising their polynucleotide as well as methods of making their polypeptide. Therefore, Claims 1, 4-7, 9, 10, 14, 15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Barton et al, 2004 (filing date 28-JAN-2003).

Claim 1, 2, 4-7, 9, 10, 12, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Takegawa et al, 1997. Takegawa et al teaches an Arthrobacter polypeptide that is a variant of SEQ ID NO: 1 and has amidase activity. Takegawa et al also teaches an Arthrobacter polynucleotide that is a variant of SEQ ID NO: 3, encodes a variant of SEQ ID

NO: 1, and has amidase activity. Takegawa et al further teaches vectors (including T7Bluescript) and microorganisms (including E. coli) comprising their polynucleotide as well as methods of making their polypeptide. Therefore, Claim 1, 2, 4-7, 9, 10, 12, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Takegawa et al, 1997.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652